Regulatory Models for Emerging Technologies

GOVERNING EMERGING TECHNOLOGIES

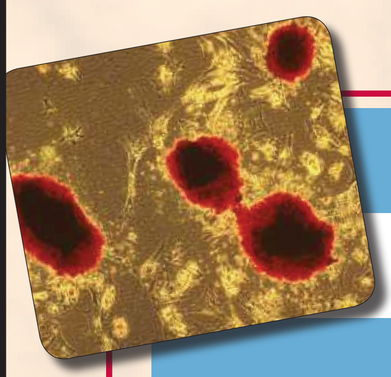
Shawn H.E. Harmon, Principle Investigator

ESRC Award No. RES-000-22-2678

THE PROJECT

OBJECTIVES: examine the values and conduct of stakeholders grappling with the myriad controversies surrounding stem cells, and enter dialogues that will reveal ambitions for the science and its associated regulatory instruments; **METHODOLOGY:** (1) desktop research; (2) stakeholder workshop; (3) mailed questionnaire followed by semi-structured interviews; **CALL FOR PARTICIPANTS:** input from all interested stakeholders is **essential**; for more on the project, see www.law.ed.ac.uk/ahrc/esrcvaluesproject; to contact the Principle Investigator, email shawn.harmon@ed.ac.uk.

Regulatory Model for Stem Cell Research: Argentina v. United Kingdom



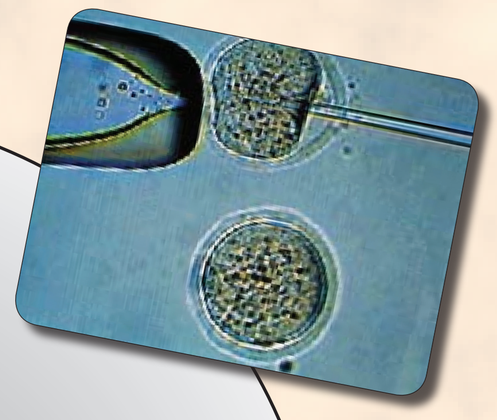
BLACK BOX MODEL

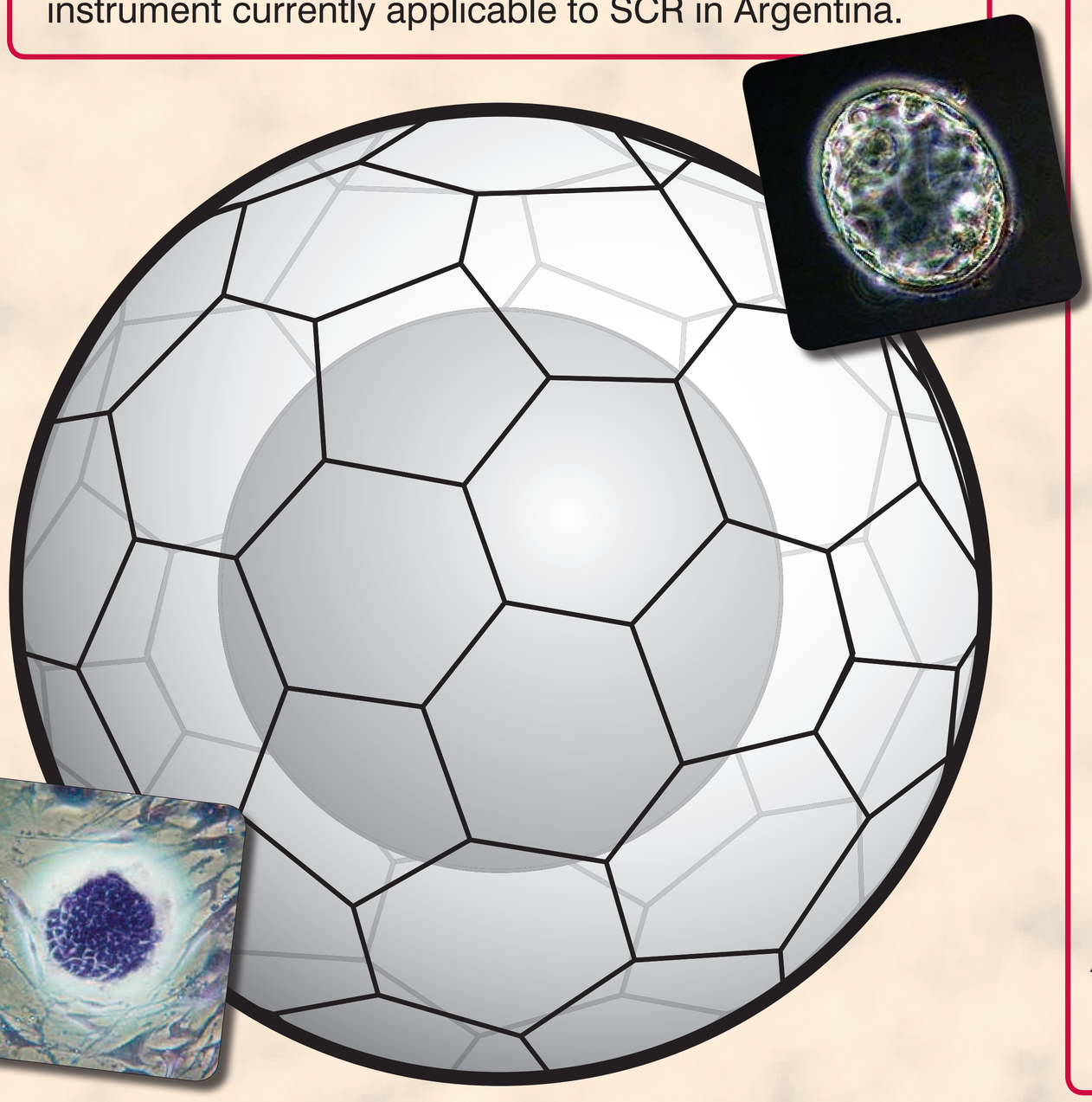
This regulatory model prohibits or encloses certain specified activity deemed to be immoral, but otherwise offers little regulatory guidance to those pursuing SCR.

SCR takes place outwith the regulatory framework (ie in the regulation's penumbra) and is therefore little influenced by it; choice of research direction remains a bottom-up process and authorities rely on individuals to police themselves and to act both virtuously and with utility.

As new processes, practices or capabilities emerge, there is no institutional means by which to measure or manage the social unease (or discord) which it incites.

This model is captured by Argentina's *Decree 200/1997: Prohibition on Human Cloning*; the only regulatory instrument currently applicable to SCR in Argentina.





MATRIX MODEL

This regulatory model envelopes SCR; any SCR occurring outwith the regulatory framework, which is monitored by statutorily-empowered regulators, is subject to clear, enforceable penalties. SCR is therefore shaped by the publicly-set regulation.

Regulation is given more work to do: it must not only clarify the scope of acceptable SCR (ie: dissuade "bad science"), but also minimise risk (ie: articulate and punish unfair research practices), encourage R&D and markets, and even manage expectations.

Legislators can more easily shrink or expand the scope of scientific endeavour with less controversy and effort.

This model is captured by the UK's complex of regulatory instruments, including the *Human Fertilisation & Embryology Act 1990* and the *HFEA Research Purposes Regulations 2001*, and will be encapsulated by the new *Human Tissue & Embryos Act*, once promulgated.